Chairman Davis thank you for giving me the opportunity to share with you something of what it is like to provide medical care for people with hepatitis C and to share with you my assessment of the effectiveness of current federal efforts to combat the disease.

Since March of 2000, I have been medical director of the Frederick County Hepatitis Clinic, Inc. This is a small not-for-profit community-based organization in central Maryland that has provided comprehensive medical care to victims of HCV – care without regard to financial status. We have now treated over 1000 patients for hepatitis C, most of them coming from marginalized populations that have no other access to care for this disease. Our patients have come from as far away as Colorado, Florida, Tennessee, Louisiana, Pennsylvania, WV, and the extremes of Maryland. They come because they are sick or afraid, or both; and they come to us because they have no other place to go.

Chronic viral hepatitis can be a very subtle disease. When symptoms are present at all they may be non-specific—like tiredness, joint and muscle aches, or depression. Often there are no symptoms at all until very late in its course. The disease starts with inflammation the liver blood vessels. Then over a period of two decades scar tissue is laid down. Eventually the walls of scar tissue coalesce, isolating the remaining liver tissue cells into little islands called follicles that have impaired access to blood and digestive systems. This is what the term cirrhosis means: scar tissue and nodules. Over time, about eight years from the onset of cirrhosis, these islands of liver cells may undergo transformation into liver cancer.

The majority of people with HCV will not suffer serious effects from the disease. However a significant minority will. JB Wong and others have projected that in the decade of 2010 to 2019, 190,000 Americans will die from this disease. This will represent a loss of 1,830,000 years of human life under the age of 65. Dr. Wong's group modeled the economic cost of the epidemic and put it at $75 billion in health care and societal costs. Twenty percent of people with chronic hepatitis will get cirrhosis: that's about 540,000 Americans. Reducing the numbers that represent disability and death is our goal. Each number represents a human life, a world of sensibilities and possibilities.

The state of Maryland will lose about twice as many people to HCV in the next 16 years as were murdered at the World Trade Center. We see this coming, and we have the means to prevent this. What does it say about us, if, when the day is done, we have not done our very best to stop it?

It seems like everyone sees this as a question of money or the lack of it. Let me tell you what the folks in Frederick County Maryland have done to combat this disease with an annual budget of 60,000 to $70,000, with one full time employee, our hard working executive director, a few part-timers, and a bunch of committed volunteers. Last year -- thanks to our strategic partners including Frederick county physicians, the Frederick Memorial Hospital, the Frederick County Health Department, Schering Plough, Roche, and other pharmaceutical companies, and a grant from our Board County Commissioners -- we distributed over $1.5 million in goods and services to our target populations. As small and fragile as we are, the clinic is now one of Maryland's largest hepatitis providers and the only source of comprehensive hepatitis care dedicated to Maryland's uninsured and under-insured. Imagine what could be done with adequate state and federal funding.

In addition to providing clinical services to the poor, we have hosted three major HCV conferences for health care providers. We have produced several multimedia programs for the general public. I will leave one of these with you, a DVD program called "Celebrating Shelley." It is a 10-minute textbook on the human impact of this disease.

Most federally funded HCV studies have not carefully examined how the disease is expressed in marginalized populations. Indeed many of these people were excluded from the NHANES survey upon which our current estimates of disease prevalence are based. These people are truly invisible to both the federal government and to academia. They are also where the burden of this disease – the prevalence, disability, and mortality of infected people – is concentrated. Our clinic targets "special" populations infected with HCV – the poor and working poor, chemically dependent, mentally ill, and HIV co-infected. They comprise a little over half our clientele. Our experience in dealing with special populations suggests that HCV tends to be especially virulent in them -- that is, more likely to produce disability and death. Effective interventions such as screening, education, vaccination, and treatment may reap even larger dividends in these high-risk populations than in the general public.

When each client first arrives at the clinic, we do a comprehensive health assessment. One of every sixteen people arrives at their fist visit with end-stage liver disease, too late for much of anything except comfort measures, transplantation, or death. Our goal is to prevent this from happening in the other 15. We educate, counsel, and support our clients. We try to figure what else is going on. Hepatitis C often does not travel alone. Do our clients have other serious physical or mental diseases? Are there current alcohol or drug problems? Could they tolerate treatment if it were necessary? We do a damage assessment. How bad is the liver scarring? A liver biopsy helps us to determine whether or not anti-viral treatment is necessary and if there is other concurrent liver disease. Is HCV causing serious problems in other areas besides liver disease? Everyone gets counseling about the natural history of the disease, about life style changes. People who are heading for cirrhosis get antiviral therapy.

Of the clients that our clinic selects for treatment, 48% have the most severe stages of viral hepatitis – stage III or IV fibrosis. This is an important indication of just how sick this invisible population is. There are hundreds of thousands of people all over the country with stage III and IV liver who are not getting any counseling, not getting any treatment.

Our clients often have a history of substance abuse and/or psychiatric issues. We must optimize treatment for these co-occurring illnesses prior to, during, and after treatment. This is both the challenge and the dividend of treating HCV in special populations. The way we look at it, helping our patients to become healthy means more than curing hepatitis C. It is also means helping our clients lose the destructive habits and mind-sets that may have lead to the disease in the first place. For some of our clients, it means learning to take care of oneself, learning to care about others, and getting back to work. Seeing this happen in our clients, again and again, is what motivates us.

Because antiviral treatment can be difficult, we provide a lot of support for our clients. The result is that 85% of those who start therapy finish it, and the majority of those that do clear the virus permanently. For them, treatment is a once and done deal. Today, HCV is the only chronic viral infection that can be called "curable."

Chairman Davis, you asked for my comments on federal efforts to combat this disease. Your Honor, if I may extend your use of the combat metaphor, let me describe the situation from the point-of-view of a platoon leader in the battlefield of HCV. Sir, our troops are getting hammered. The battle plans that have been drawn up in the form of NIH consensus statements and CDC guidelines have not been implemented. The field soldiers are out of ammunition and there is no food for the troops. The few units that remain in action must scrounge for food and ammo in the wilderness. Let me illustrate these points from my experience as a Maryland physician.

The state of Maryland, mind you, is not a poor state. We are national leaders in both biomedical research and in medical education. Our governor, Robert Ehrlich, a distinguished former member of this body, is Maryland's first governor to begin addressing Hepatitis C. We are very excited about having a governor who is willing to address this disease.

However, let me share with you a few surprising facts about the past, present, and future of HCV in Maryland, a condition which our governor inherited. I serve as a current member of Governor Ehrlich's Hepatitis Advisory Council and have learned a lot about how Maryland sees this epidemic. HCV is Maryland's second most commonly reported infectious disease. It has already infected 100,000 Marylanders, of whom at least 20,000 will develop cirrhosis and 5000 will die. It will cost the state over $2 billion in health care and societal costs over the coming years.

Yet Maryland's Department of Health and Mental Hygiene, following the federal government's "lead" on HCV, has not one person in the entire state government designated to work on HCV. In the 16 years since the virus has been identified, the State of Maryland has yet to spend $1 for HCV control or education programs.

Maryland presently denies about 90% of its 8-10,000 HCV-infected inmates access to *any* screening, education, or treatment for HCV. Maryland does get federal funds for HIV treatment, and some of those funds can be used to treat HCV in co-infected patients. (HCV is a major cause of death in HIV patients). However, inmates without HIV get nothing. They have the right to remain permanently silent-- the right to die of a treatable disease.

The net result of the federal funding policy at the state level is a human rights and legal liability nightmare. Our current policy of purposeful failure to identify HCV in at-risk inmates without HIV – a don't-ask-don't-tell policy – and denying access to basic health care based on a negative HIV status – will be successfully challenged. Our state, and others like it, will be found negligent and liable for damages unless they stop this policy now. All states, not just Maryland, need clear ethical, cost-effective, legally defensible, and scientifically sound mandates for care of HCV in inmate populations AND they need adequate federal funding to implement them. And if we do it for inmates, because we must, I think we should do it for people on the other side of prison bars, because we can.

Congress can improve its efforts in combating HCV and other infectious diseases by addressing the process by which health care funding is allocated – making certain that the diseases that are the most prevalent, costly, lethal, and responsive to intervention receive priority funding. However, effective HCV intervention will require more than federal funds. It will require a degree of cooperation between the mental health, addictionology, prison and public health, and infectious disease disciplines that has never

before been achieved. It will require the development of fully integrated, crosscutting teams that work well together instead of competing at the funding troughs. Unless this type of platform for cooperation is crafted into the wording of funding proposal goals and objectives, results will be sub-optimal -- money and lives will be wasted.

Congress may want to look at allocating funds for HCV training programs in primary care teaching settings. Family practice, internal medicine, nurse practitioner, and physicians' assistant training programs can easily integrate HCV treatment into existing in-house substance abuse, STD, HIV, and mental illness programs to provide the total package necessary for optimizing clinical outcomes. Graduates of these programs will be in a good position to provide cutting edge services for the communities that they will serve for years to come. Currently, gastroenterologists usually handle this disease. I think this has been a mistake. This epidemic is too big and too complex. Our nation's history of handling this disease up until now speaks for itself: we must train and involve people who understand human, family, and community dynamics – who treat patients as a whole. If there was ever a condition that requires the mindset of a trained primary care provider, it is hepatitis C.

These interventions and others you will hear about will make a big difference in battle against hepatitis C. Done correctly, they will also strengthen our entire public health infrastructure. On behalf of all the people with HCV, their families and friends, I respectfully implore you, Congressmen, please help us. We need your help -- not just federal funding but federal leadership--and we need it now. Thank you for your attention.

Respectfully Submitted

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